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Effectiveness of Functional Electrical Stimulation on shoulder subluxation and shoulder pain in patients with hemiplegia.

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A B S T R A C T

Introduction: Good shoulder function is a prerequisite for effective hand function, as well as for performing multiple tasks involving mobility, ambulation, and activities of daily living (ADL). Subluxation of the glenohumeral joint is a well-recognized complication experienced by stroke patients. The reported incidence of shoulder subluxation varies greatly, from 17% to 81%. The vulnerability of the glenohumeral joint to subluxation is a function of the anatomy of the joint.

Purpose: To investigate the effect of functional electrical stimulation (FES) for the treatment of shoulder subluxation and shoulder pain in hemiplegic patients.

Design:- An experimental pretext – posttest study design was used.

Method: A total of 30 hemiplegic patients with shoulder subluxation and shoulder pain were included in the study. The patients were randomly divided into the study and control groups. All patients were put on a rehabilitation program using conventional methods while the study group patients were additionally applied FES to supraspinatus and posterior deltoid muscles. The shoulder pain of all patients during resting, passive range of motion (PROM) and active range of motion (AROM) was measured with the visual analog scale (VAS) while the shoulder subluxation levels were evaluated on anteroposterior shoulder X-ray before and after the treatment and rehabilitation program and compared.

Results: Comparison of the resting AROM vs. PROM VAS value changes showed significant difference between the groups. There was a significant difference between the two groups for the amount of change in shoulder subluxation in favor of the study group.

Conclusions: The results of our study have shown that applying FES treatment to the supraspinatus and posterior deltoid muscles in addition to Bank of exercise specific training treatment when treating the subluxation in hemiplegic patients is more beneficial than Bank of exercise specific training by itself.

Keywords: Subluxation, Shoulder pain, stroke, functional electrical stimulation (FES), glenohumeral, muscle tone

1. Introduction

The WHO define stroke as an acute neurologic dysfunction of vascular origin with symptom & sign corresponding to the environment of focal areas of the brain. CVA results in upper motor neuron dysfunction that produce hemiplegic or paralysis of one side of the body including limbs & trunk and sometimes the face and oral structures that are contra lateral to the brain hemisphere.

Good shoulder function is a prerequisite for effective hand function, as well as for performing multiple tasks involving mobility, ambulation, and activities of daily living (ADL). A common sequel of stroke is hemiplegic shoulder pain that can hamper functional recovery and subsequently lead to disability. Poduri, (2007) reports that hemiplegic shoulder pain can begin as early as 2 weeks post stroke but typically occurs within 2-3 months poststroke.1

Subluxation of the glenohumeral joint is a well-recognized complication experienced by stroke patients. The reported incidence of shoulder subluxation varies greatly, from 17%1 to 81%.2 The vulnerability of the glenohumeral joint to subluxation is a function of the anatomy of the joint. As an extremely mobile joint, it sacrifices stability for mobility.3 Basmajian4 determined through electromyographic studies that the supraspinatus, and to a lesser extent the posterior deltoid muscles, played a key role in maintaining glenohumeral alignment. Chaco and Wolf5 also demonstrated the importance of the supraspinatus muscle in preventing downward subluxation of the humerus.

The inferior subluxation of the head of the humerus, a common and serious problem in hemiplegic, has been reported with an incidence ranging from 31% to 80% in stroke patients.1-3 It represents an etiologic factor in the painful shoulder, a complication even more frequent in hemiplegic subjects.4,5 Although the etiology is not well elucidated, the paralysis of the shoulder muscles and the resulting atrophy seem to play important roles.

Shoulder pain is a frequent and debilitating symptom in hemiplegic patients.1-3 It usually starts the second week after stroke, but could start earlier or later. There are many factors that contribute to shoulder pain in the hemiplegic patient. Some are related to the neurologic lesion, such as the lack of sensibility and unilateral neglect. Other factors are related to the joint, such as lesion of the rotator cuff tendons, reflex sympathetic dystrophy, spasticity, or shoulder subluxation.1-3

Traditionally, slings have been applied to prevent or reduce shoulder subluxation after stroke. The most effective slings have the drawback of holding the limb in a poor position that is likely to cause soft tissue contracture and have a disadvantageous effect on symmetry, balance, and body image.6 7 8 9In view of the shortcomings associated with the use of slings, alternative approaches to deal with this problem have been sought. Two studies10 11 have investigated the application of electrical stimulation to the supraspinatus and posterior deltoid muscles.

Faghri et al11 recruited 26 patients on average 17 days after stroke and allocated them randomly to experimental and control groups. Subjects in the experimental group demonstrated a mean subluxation of 6 mm on initial x-ray, and the control group showed a mean subluxation of 4 mm. The experimental group received a program of electrical stimulation for 6 weeks, followed by a no treatment period of 6 weeks. Baker and Parker10 used a similar method in their study of 63 subjects, with the main difference being that all subjects had a chronic subluxation of at least 5 mm compared with the unaffected arm. Both studies demonstrated a beneficial effect on subluxation over the treatment period, with that Faghri et al11 showing improvement in other parameters, such as pain, range of motion, and arm function. However, both studies showed deterioration following withdrawal of electrical stimulation, although not back to pretreatment levels.

The use of functional electrical stimulation (FES) aimed at reducing subluxation of the hemiplegic shoulder was first used about a decade ago. At that time, a small group of hemiplegic subjects were followed for a relatively short period of time. 7,8 More recently, Faghri and associates' described the effectiveness of FES on shoulder subluxation, arm function recovery, and shoulder pain in hemiplegic stroke patients. These authors believed the FES overcame the painful hemiplegic shoulder because it is well known that the electrical therapy has a strong sedative effect on pain by acting on sensory nerves. Furthermore, a different kind of electrical current may have an action on muscle fibers. This could reinforce the trophicity and the strength in the stimulated muscles. At the same time that Faghri' was studying the effect of FES on shoulder pain in stroke patients.

A few case-series13-15 and a randomized controlled clinical trial that included 22 patients16 combined the stimulation with both unimanual and bimanual task-oriented functional activities. The combination is most appropriately termed functional electrical stimulation (FES).

The etiopathogenesis of shoulder pain in the hemiplegic patient is not yet fully understood. The subluxation may be one of the factors contributing to pain, but further studies are required to better understand the occurrence of this subluxation.Motor deficit and muscular hypotonia of the shoulder present at the onset of hemiplegia most certainly play roles in the development of shoulder pain.7 Faghri' described the mechanism by which the muscles contribute to the pathogenesis.

The muscle tone problem can also be worsened by the presence of injury to the rotator cuff, leading to a more fragile structure.12 Finally, the weight of the upper limb itself increases the downward pull, further decreasing the congruency of the joint, thus possibly causing the shoulder pain3 Recently, Joynt9 suggested that the subacromial area of the shoulder could be a location of the pain-producing structure. All these factors may contribute to the pain occurring in the hemiplegic shoulder.

In one of the first studies using FES on hemiplegic shoulder, Baker and Parker7 showed an improvement of the painful shoulder and subluxation after 6 to 8 weeks of treatment.Faghril successfully used FES to overcome the painful hemiplegic subluxed shoulder.FES also seems to speed up motor recovery, which is consistent with the observations of Faghri.

In this study an attempt has been made to test the effectiveness of FES and to see its effect on the shoulder subluxation and shoulder pain of patients with cerebrovascular accident.

2. Aims and Objectives

Aims- To establish whether intervention with functional electrical stimulation (FES) has any influence on subluxation and shoulder pain in hemiplegia**.**
Objectives- To evaluate the effect of FES on upper extremity function**.**

3. Hypothesis

Experimental: There will be more improvement in shoulder subluxation and shoulder pain by giving conventional therapy combined with FES than only conventional therapy in the patients with hemiplegia.
Null hypothesis: FES does not have any effect on shoulder subluxation and shoulder pain in patients With Hemiplegia.

4. Methodology

DESIGN- Comparative pre-test post-test experimental research design having control and experimental group. The control group was given conventional therapy alone and experimental group received conventional therapy along with FES.

SUBJECT- 30 subjects with age group of 30-75 years with 6 months of Hemiplegic having shoulder subluxation and shoulder pain were screened as potential candidates .By using Initial Occupational Therapy Assessment, 30 patients were included in the study.

PERIOD- Study period of 12 months was allotted.

SETTING- Out-patient and in-patient based clinical settings. The study was conducted at department of occupational therapy, NIOH, Kolkata.

ETHICAL ISSUES- On the basis of earlier studies using FES the risk factors and adverse effect of this study on the Hemiplegic patients was found to be minimal or absent. The ethical committee meeting held at N.I.O.H gave their approval for this study to be undertaken in the institute itself.

INCLUSION CRITERIA-

- Age group of 30-75 year.
- Adult hemiplegia cases with tone between 1 to 1+ (According to Modified Ashworth Scale)
- Medically stable patients.
- No contracture or deformity in hand.
- No hyper sensitivity for the external stimulus.
- Adequate language function to respond to a two step command.

EXCLUSION CRITERIA-

- Having cardiac complications.
- Acute reflex sympathetic dystrophy.
- Any comorbid neurological disease.
- Unhealthy skin condition or allergies.
- Inability to sit in a standard armless chair for 30-minutes.

OUTCOME MEASURES -

- VAS for pain
- Fugal Meyer performance assessment scale
- X -ray for evaluating the shoulder subluxation.

5. Procedure

Written consent to participate was obtained from all subjects after explanation of test procedures and the rights of human subjects. As per the inclusion criteria 30 subjects were selected for the study divided into two groups (Control & Experimental) of 15 each. Subjects who consented to participate were interviewed to obtain demographic information and were assessed according to the general assessment format.
Subjects of both the groups were then clinically scored by the finger breadth method (which has 90% agreement with X-ray regarding the presence of subluxation, Hall J 1995) for subluxation by seating them erect on a chair. The subject's arms were unsupported at their sides in natural rotation. A presence of subluxation was noted if there was a palpable space in between the acromion process and the head of humerus. Both the groups were assessed

with Fugal meyer assessment of physical performance, Visual Analog Scale for pain and grade of shoulder subluxation radiographically. The X-rays were graded by an orthopaedic surgeon. (Figure)

At the very beginning the subjects of experimental group were suggested to use FES for 1-2 days as a trial to acquainted with the device. Pre test score was recorded for the both group using the Fugal meyer of performance, Shoulder subluxation gradation and VAS as a baseline measurement. The control group followed a standardized bank of exercise and the experimental group followed the same standardized bank of exercise that was synchronized with Electrical stimulation (Digistim EMS 2-Channel) and induced contraction of supraspinatus fossa and the posterior aspect of the upper arm to stimulate the supraspinatus and posterior deltoid muscles. The exact pattern of exercise varied from individual to individual being based on the clinical judgment of the researchers. The contraction length was 5 second with a 3 second rest period. The skin surface electrodes with Meditech gel (commercial name) were used for better conduction and comfort of the subjects. Surface electrode ranging in size 2 x 2 cm in steel / 1.5 inch rubber pad in diameter / pen electrode chosen as per requirement and were positioned over the supraspinatus fossa and the posterior aspect of the upper arm to stimulate the supraspinatus and posterior deltoid muscles.

Both the groups received 45 minutes training session in a day having 5 minutes of stretching and passive movements. In experimental group the FES stimulation session was 40 minutes (3 ten minutes stimulation and two 5 minutes break interval in between) with bank of exercise. The control group engaged in 40 minutes of bank of exercise without electrical stimulation. Duration of the treatment is 5 session per week for 4 weeks (20 sessions). After completion of 20 sessions post test for each variable was taken for analysis .The (flow chart) shows the process of intervention.

The training protocol for both the group was composed of individually structured and guided Occupational Therapy aimed at promoting motor retraining of paralyzed and tight muscles of wrist and hand.

Functional tasks and activities were individually tailored. The training was also constructed from selection of appropriate exercises from exercise bank. Number and complexities of exercise were adjusted by Occupational Therapist for each patient so that he/she was able to practice independently or with assistance from a family member.

6. Bank of Exercises (Task Specific Training)

The list contains both simple and more complex tasks and upper extremity functional exercises.

1. PASSIVE/ACTIVE ROM

1) Passive ROM: wrist/elbow/shoulder, self or by family member
2) Active/assistive ROM: wrist/elbow/shoulder bilateral with dowel, cane
3) Active ROM: wrist/elbow/shoulder in sitting and standing
4) Active ROM with resistance: wrist/elbow/shoulder in sitting and standing

2. WEIGHT BEARING AND SUPPORTIVE REACTION

1) Seated weight bearing (forearms on tabletop) with affected upper extremity
2) Extending arms, seated or standing with bilateral upper extremity weight bearing on table
3) Extended arms with transitional movements: side lying to sit, sit to stand, dips
4) Extended arms and wrist/hand on wall from anterior and lateral, progress to wall push up
5) Extended arms and wrist/hand on wall with change in base of support; example: weight shifting, single lower extremity support, lateral wall walking

3. REACHING ACTIVITIES

1) Forward supported reach bilaterally with cane on tabletop (elbow extension)
2) Forward supported reach with shoulder elevation, elbow/wrist extension
3) Reaching against gravity in frontal and sagittal planes
4) Reaching overhead with active wrist/hand movements
5) Dynamic reaching to a target; example: catch a ball

4. GRASPING, HOLDING AND RELEASE

1) Maintaining digit extension with weight bearing
2) Grasp, hold and release containers with gravity minimized (on table)
3) Pick up and move/release small object on table
4) Pick up and move/release large objects without proximal support
5) Incorporate key and pinch grips in hold and release including stacking, lifting and overhead activity

5. UPPER EXTREMITY ADL

1) Dressing, grooming
2) Carrying objects with bilateral upper extremities
3) Opening bottles, stabilizing with paretic extremity for reaching
4) Writing, drawing, manipulating small objects
5) Folding towels, sweeping, hanging towels, setting table

6) Simulated self-feeding
7) Pre-work activities (assembling tasks / secretarial task)
ROM range of motion; ADL activity of daily living.

7. Statistical Analysis

Sample t test was used to analyse changes among group.Continuous data will be analyzed using t-tesoxon test and discrete data will be analyzed using Mannwnitney and Wilcoxon test.
Level of significance will be set at $p<0.05$ with 95% confidence interval.
Data were presented as arithmetic means +/- standard deviation(X+/-SD).

8. Results

A total number of 30 Hemiplegic patients were recruited for the study with age range from 30 to75 years. There were 22 male and 8 female patients in the study. There was no drop out during the study. Data were collected at the 1st day visit and after the completion study.

Table-1: (Demographic Data) shows the distribution of patients in both experimental and control group.

SL NO	Baseline Characteristics	Experimental Group	Control Group
1	No of Subjects	15	15
2	Age range(years)	30-75	30-75
3	Mean age(SD)	42.13(10.07)	44.13(10.676)
4	Sex(Male/Female)	11/4	11/4

Table.1 depicts that in Experimental group mean age is 42.13years and standard deviation of 10.07.In Control group mean age is 44.13years and standard deviation of 10.676.Experimental Group and Control Group consists of 11male and 4 female subjects's each. From above table it signifies both the group shows the same baseline characteristics.

Table-2A: Within group analysis of Fugal Meyer.

GROUP	PRE(mean+sd)	POST(mean+sd)	t	P
CONTROL	21.66(5.715)	22.66(6.478)	1.82	0.089
EXPERIMENTAL	22.11(5.976)	41.21(7.22)	14.15	0.001

Table-2A depicts the within group analysis of Fugal meyer shows the base line characteristics of the both the group are same i,es pre value of both group, control and experimental are 21.66 with standard deviation of 5.715 and 22.11 with standard deviation of 5.976 respectively. The post value of experimental and control group was 41.21 with standard deviation of 7.22 and 22.66 with standard deviation of 6.478 respectivly.
The result of the comparison of Fugal meyer with in group analysis was found to be significant. In control group the t value 1.82 and the p value 0.089, which shows that there is no significant improvement in hand function in control group. In experimental group the t value was 14.15 and the p value was 0.001, which suggest that there is marked improvement in hand function.

Table-2B: Between the group analysis of Fugal meyer.

CONTROL(mean+sd)	EXPERIMENTAL(mean+sd)	T	P
22.66(6.478)	41.21(7.22)	7.332	0.000

. Table-2B depicts between the group analysis of fugal meyer of both the group,shows the t value was 7.332 and p value was 0.000,which suggests that there was significant improvement in hand function in experimental than that of control group.

Table.3A: Within group analysis of Shoulder Subluxation.

GROUP	PRE(mean+sd)	POST(mean+sd)	T	P
CONTROL	1.933(0.798)	2.066(0.801)	0.807	0.433
EXPERIMENTAL	2.20(0.941)	1.266(0.723)	3.22	0.006

Table-3A depicts the within group analysis of Shoulder subluxation shows the base line characteristics of the both the group are same i,es pre value of both group, control and experimental are 2.20 with standard deviation of 0.941and 1.933 with standard deviation of 0.798 respectively. The post value of experimental and control group was 1.266 with standard deviation of 0.723 and 2.066 with standard deviation of 0.801 respectively.
The result of the comparison of Shoulder subluxation with in group analysis was found to be significant. In control group the t value 0.807 and the p value 0.433, which shows that there is no significant improvement in shoulder subluxation in control group. In experimental group the t value was 3.22 and the p value was 0.006, which suggest that there is marked improvement in shoulder subluxation.

Table.3B: Between the group analysis of Shoulder Subluxation.

CONTROL(mean+sd)	EXPERIMENTAL(mean+sd)	T	P
2.066(0.801)	1.266(0.723)	3.39	0.002

Table-3B depicts between the group analysis of shoulder subluxation of both the group, shows the t value was 3.39 and p value was 0.002,which suggests that there was significant improvement in shoulder subluxation in experimental than that of control group.

Table.4A: Within the group analysis of VAS.

GROUP	PRE(mean+sd)	POST(mean+sd)	t	P
CONTROL	8.556(0.784)	8.106(0.772)	4.216	0.061
EXPERIMENTAL	8.59(0.531)	1.020(0.485)	9.281	0.001

Table-4A depicts the within group analysis of Shoulder pain(VAS) shows the base line characteristics of the both the group are same i,es pre value of both group, control and experimental are 8.59 with standard deviation of 0.531and 8.556 with standard deviation of 0.784 respectively. The post value of experimental and control group was 1.020 with standard deviation of 0.485 and 8.106 with standard deviation of 0.772 respectively.
The result of the comparison of Shoulder pain (VAS) with in group analysis was found to be significant. In control group the t value 4.216 and the p value 0.061, which shows that there is no significant improvement in shoulder pain in control group. In experimental group the t value was 9.281 and the p value was 0.001, which suggest that there is marked improvement in shoulder pain. (VAS)

Table.4B: Between the group analysis of VAS.

CONTROL(mean+sd)	EXPERIMENTAL(mean+sd)	t	P
8.106(0.772)	1.020(0.485)	7.98	0.001

Table-4B depicts between the group analysis of shoulder pain(VAS) of both the group, shows the t value was 7.98 and p value was 0.001,which suggests that there was significant improvement in shoulder pain(VAS) in experimental than that of control group.
Here introduce the paper, and put a nomenclature if necessary, in a box with the same font size as the rest of the paper. The paragraphs continue from here and are only separated by headings, subheadings, images and formulae. The section headings are arranged by numbers, bold and 9.5 pt. Here follows further instructions for authors.

9. Discussion

9.1 Shoulder Subluxation

The results of this Study show that the application of FES in addition to Bank of exercise specific training is superior to Bank of exercise specific training alone in the prevention or treatment of shoulder subluxation early (less than 6 months) but not late (more than 6 months) after stroke.
However, the results of the late application of FES should be interpreted with caution because of the low number of studies included as well as the low observed power of the meta-analysis. These results are consistent with those presented in the review by Adam and Foongchomcheay [15].
The conventional treatment of shoulder subluxation, especially during the flaccid phase when there is no active contraction of deltoid and supraspinatus, may include using a traditional sling and arm support that prevents shoulder subluxation or employing preventive measures such as early range of motion exercises, proper positioning, and passive support of soft tissue structures. In contrast, FES directly stimulates the nerves of the paralyzed muscles and produces contraction in those muscles. Therefore it seems very unlikely that the additional treatment time could be responsible for the reduction of subluxation in the FES group, compared to the control group. These changes need to be seen as a direct effect of FES.
There have been debates among investigators on the short- and long-term effects of FES in stroke patients. Although most authors agree on the short-term effects of FES, not everyone agrees on its long-term effects. Such controversy in the results has been reported in a meta-analysis by Robbins et al. [17].

The results of our review are strongly suggestive of the short-term effects of FES but are inconclusive about the long-term effects. More good quality studies are needed, in order to reach conclusive results about the long-term effect of FES therapy on shoulder subluxation.

9.2 Pain

Ada and Foongchomcheay [15] reported no effect of FES therapy on shoulder pain early (less than 2 months) after stroke but reported a significant effect of FES late (more than 2 months) after stroke. The results of this study show that FES is superior to conventional therapy alone for the reduction of shoulder pain. The findings of the two meta-analyses for the studies that measured pain functionally (pain-free range of lateral rotation) and those that measured pain with self-report measurement scales (numerical pain scale, VAS) showed significant difference between the experimental and control groups. Only one of the three studies showed an improvement in the pain-free ROM. On the other hand, self-report pain assessments are methods that have been used in more recent studies, which can better indicate the patients' overall feeling of pain. Therefore any result measured with a self-report scale in stroke patients should be treated with caution. The results of this review are inconclusive about the effect of FES on shoulder pain late after stroke. This is due to a very low number of studies that have applied FES late (more than 6 months) after stroke.

9.3 Motor Function

The findings of this review show that FES therapy have a significant effect on upper arm motor function early after stroke compared to conventional therapy alone. In the retrieved articles that evaluated motor function early after stroke, the measures of motor function varied greatly. Levin et al. [17] suggest that there should be a distinction between clinical impairment and function measures. Impairment scales measure specific motor aspects that are not related to task accomplishments (spasticity, strength, and isolated joint motion), whereas functional scales measure the level of task success (jar opening, key turning)]. In this review we found that the group of studies that had reported a significant effect of FES on motor function used methods that measure impairment, not function or activity. For example Wang-E used the Fugl-Mayer Assessment, which only measures isolated joint motion and is considered as an impairment measure. However, it is not clear if such improvements in muscle activity and joint motion can be translated to improvement in motor function. On the other hand, in the group of studies that have found no superiority of FES over conventional therapy, there are good quality articles that have mostly used those assessment methods that measure function or activity instead of impairment.
Therefore more studies looking at functional measures are needed in order to reach a broad conclusion about the effects of FES on upper arm motor function late after stroke.

10. Conclusion

The purpose of this paper was to that estimated the extent to which FES impacts on shoulder subluxation, pain, and upper arm motor function in stroke patients. The findings suggest that initiating the FES treatment early after the incidence of stroke can significantly reduce the level of shoulder subluxation. Such an effect is mostly observed during the treatment period, not after a follow-up period. More research is still required to examine possible long-term effects of FES therapy on shoulder subluxation. Furthermore, the results of this suggest that FES have effect on pain compared to conventional therapy alone if applied early after stroke. The results of this further show that FES therapy early after stroke is not superior to conventional therapy alone in the restoration of motor function in the upper arm. Due to the low number of studies, the results are inconclusive about the FES effectiveness late after stroke.

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